IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

POZEN INC.	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 6:11-cv-0272-LED
	§	
SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., CARACO PHARMACEUTICAL LABORATORIES LTD.	§	PATENT CASE
	§	
	§	
	§	
Defendants.		

THIRD AMENDED COMPLAINT

Plaintiff Pozen Inc. ("Pozen") complains against Sun Pharma Global FZE ("Sun FZE"), Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), and Caraco Pharmaceutical Laboratories Ltd. ("Caraco") (collectively, the "Defendants") and alleges the following:

The Parties

1. Pozen is a Delaware corporation, having its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517. Pozen is a specialty pharmaceutical company dedicated to developing therapeutic advancements for diseases with unmet medical needs. Pozen currently specializes in innovative drug products designed to alleviate patient pain and suffering.

2. On information and belief, Sun FZE is a corporation organized under the laws of the United Arab Emirates having corporate offices at Office No. 43, Block-Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

3. On information and belief, Sun Ltd. is a corporation organized under the laws of India, having corporate offices at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, India 400 059.

4. On information and belief, Caraco is a Michigan corporation and a licensed distributor of pharmaceuticals with the Texas Department of State Health Services that maintains its headquarters at 1150 Elija McCoy Drive, Detroit, Michigan.

5. According to Sun FZE, it is a wholly owned subsidiary of Sun Pharma Global, Inc., which is in turn a wholly owned subsidiary of Sun Ltd. [Docket No. 11 at p. 1] .

6. On information and belief, Caraco is a subsidiary of Sun Ltd. and Sun Pharma Global, Inc.

7. On information and belief, Sun Ltd. conducts business through and with Sun FZE.

8. On information and belief, Sun Ltd. conducts business through and with Caraco.

9. On information and belief, Sun FZE conducts business through and with Caraco.

10. On information and belief, Sun Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the United States including within the State of Texas.

11. On information and belief, Sun FZE is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the United States including within the State of Texas.

12. On information and belief, Caraco is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products in the United States including within the State of Texas.

13. On information and belief, and consistent with their practice with respect to other generic products, Sun FZE acted as the agent of Sun Ltd. and assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application ("ANDA") No. 202-803 concerning a proposed generic version of Treximet®.

14. On information and belief, Caraco acted and continues to act as the agent of Sun FZE for ANDA No. 202-803 concerning a proposed generic version of Treximet®.

15. On information and belief, and consistent with their practice with respect to other generic products, Sun Ltd. aided, abetted and/or actively encouraged Sun FZE to file ANDA No. 202-803 with the FDA.

16. On information and belief, and consistent with their practice with respect to other generic products, Caraco aided, abetted and/or actively encouraged Sun FZE to file ANDA No. 202-803 with the FDA.

17. On information and belief, and consistent with their practice with respect to other generic products, Sun Ltd. participated in the work related to the submission of ANDA No. 202-803 to the FDA.

18. On information and belief, and consistent with their practice with other generic products, if ANDA No. 202-803 is approved, it is the intention of Sun FZE and Sun Ltd. that the ANDA product which is the subject of ANDA No. 202-803 will be manufactured by Sun Ltd.

19. On information and belief, and consistent with their practice with other generic products, if ANDA No. 202-803 is approved, it is the intention of Sun FZE and Sun Ltd. that the ANDA product which is the subject of ANDA No. 202-803 will be marketed and sold in

the State of Texas by Caraco as an alternative to the Treximet® product currently being sold in the State of Texas.

20. On information and belief, Sun Ltd. and Sun FZE derive a substantial portion of their revenues from the sales of drugs in the State of Texas.

Nature of the Case

21. This is an action for infringement of United States Patent Nos. 6,060,499 ("the '499 patent") (a true and correct copy is attached hereto as Exhibit A), 6,586,458 ("the '458 patent) (a true and correct copy is attached hereto as Exhibit B) and 8,022,095 ("the '095 patent") (a true and correct copy is attached hereto as Exhibit C). This action is based on the Patent Laws of the United States as found in 35 U.S.C. § 100, *et seq*.

Jurisdiction and Venue

22. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), (d) and 1400(b).

23. On information and belief, Sun FZE is subject to personal jurisdiction in the State of Texas because, among other things, Sun FZE (itself and/or through its parents, agents and/or affiliates, including Sun Ltd. and Caraco) has purposefully availed itself of the benefits and protections of the laws of the State of Texas such that it should reasonably anticipate being haled into court here. On information and belief, Sun FZE filed ANDA No. 202-803 with the purpose of securing the right to sell a generic copy of Pozen's patented Treximet® product in the State of Texas. On information and belief, Sun FZE is the owner of at least 25 approved applications to market pharmaceuticals in the United States. On information and belief, Sun FZE (itself and/or through its parents, agents and/or affiliates, including Sun Ltd. and Caraco) markets and sells generic drugs

throughout the United States and in particular within the State of Texas, and therefore Sun FZE transacts business within the State of Texas such that it has engaged in systematic and continuous business contacts within the State of Texas.

24. On information and belief, Sun Ltd. is subject to personal jurisdiction in Texas because, among other things, Sun Ltd. (itself and/or through its subsidiaries, agents and/or affiliates, including Sun FZE and Caraco) has purposefully availed itself of the benefits and protections of the laws of the State of Texas such that it should reasonably anticipate being haled into court here. On information and belief, Sun Ltd. was involved in the filing of ANDA No. 202-803 with the purpose of securing the right to sell a generic copy of Pozen's patented Treximet® product in the State of Texas. On information and belief, Sun Ltd. (itself and/or through its subsidiaries, agents and/or affiliates, including Sun FZE and Caraco) markets and sells generic drugs throughout the United States and in particular within the State of Texas, and therefore Sun Ltd. transacts business within the State of Texas such that it has engaged in systematic and continuous business contacts within the State of Texas. In addition, Sun Ltd. is subject to personal jurisdiction in Texas because, on information and belief, it controls and dominates Sun FZE and therefore the activities of these companies in this jurisdiction are attributed to Sun Ltd.

25. On information and belief, Caraco is subject to personal jurisdiction in the State of Texas because, among other things, Caraco (itself and/or through its parents, agents and/or affiliates, including Sun FZE and Sun Ltd.) has purposefully availed itself of the benefits and protections of the laws of the State of Texas such that it should reasonably anticipate being hauled into court here. On information and belief, Caraco was involved in the filing of ANDA No. 202-803 with the purpose of securing the right to sell a generic copy

of Pozen's patented Treximet® product in the State of Texas. On information and belief, Caraco (itself and/or through its parents, agents and/or affiliates, including Sun FZE and Sun Ltd.) markets and sells generic drugs throughout the United States and in particular within the State of Texas, and therefore Caraco transacts business within the State of Texas such that it has engaged in systematic and continuous business contacts within the State of Texas. Caraco is also a licensed distributor of pharmaceuticals with the Texas Department of State Health Services.

26. Sun FZE, Sun Ltd., and Caraco are hereinafter referred to collectively as "Sun."

27. Pozen incorporates by reference herein its Opposition, Surreply, and Supplemental Opposition to Sun's Motion to Dismiss Plaintiff's First Amended Complaint or, in the Alternative, to Transfer Venue. [Docket Nos. 41-43, 50, and filed concurrently].

Background

28. On May 9, 2000, the United States Patent and Trademark Office ("PTO") issued the '499 patent, entitled Anti-migraine Methods and Compositions Using 5-HT Agonists with Long-Acting NSAIDS. The '499 patent issued to Pozen as the assignee and is currently assigned to Pozen.

29. On July 1, 2003, the PTO issued the '458 patent, entitled Methods of Treating Headaches Using 5-HT Agonists in Combination with Long-Acting NSAIDS. The '458 patent issued to Pozen as the assignee and is currently assigned to Pozen.

30. On September 20, 2011, the PTO issued the '095 patent, entitled Methods of Treating Headaches Using 5-HT Agonists in Combination with Long-Acting NSAIDS. The '095 patent issued to Pozen as the assignee and is currently assigned to Pozen.

31. On April 15, 2008, the FDA approved Pozen's New Drug Application ("NDA") for Treximet®, NDA No. 21-926. Treximet® is a tablet for oral administration and contains 85 mg of sumatriptan (present as a succinate) and 500 mg of naproxen sodium.

32. Treximet® is approved for the acute treatment of migraine attacks with or without aura.

33. Pursuant to 21 U.S.C. § 355(b), Pozen submitted patent information for the '499, '458 and '095 patents for inclusion in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." The FDA thereafter listed the '499, '458 and '095 patents in the Orange Book in connection with the Treximet® NDA.

34. On information and belief, Sun filed papers with the FDA allegedly constituting an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet®. On information and belief, the FDA assigned Sun's ANDA submission ANDA No. 202-803.

35. On information and belief, Sun's ANDA No. 202-803 product is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter referred to as the "Generic Product").

36. On information and belief, it is the intention of Sun that the Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

37. On April 15, 2011, Pozen received a letter from counsel for Sun (the "Notice Letter") advising that Sun had submitted ANDA No. 202-803 to the FDA and that its ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as a Paragraph IV Certification, that, in Sun's opinion, certain claims of the '499 and '458 patents are invalid and/or will not be infringed by the commercial

manufacture, use, offer to sell or sale within the United States, or importation into the United States, of the product that is the subject of the ANDA No. 202-803.

38. The Notice Letter also advised that Sun intends to market the Generic Product before the expiration of the ’499 and ’458 patents.

Related Case

39. On October 12-15, 2010, this Court held a bench trial in a related case in which Pozen presented evidence that the submission of similar ANDAs to the FDA, by Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd. and Dr. Reddy’s Laboratories, Inc., to market generic copies of Treximent® infringed certain claims of the ’499 and ’458 patents. *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, Case No. 6:08-CV-437. Pozen also presented evidence that these patents are valid and enforceable.

40. On August 5, 2011, this Court found the ’499 and ’458 patents to be valid and enforceable, and also found that Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd. and Dr. Reddy’s Laboratories, Inc. infringed the asserted claims of these patents. [Case No. 6:08-CV-437, Docket No. 416]. This Court enjoined Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd. and Dr. Reddy’s Laboratories, Inc. from making, using, selling or offering to sell their ANDA products in the United States, or importing their ANDA products into the United States, until the expiration of the ’499 and ’458 patents. This Court also set the effective dates of the approval of the ANDAs of Defendants Par Pharmaceutical, Inc., Alphapharm Pty Ltd. and Dr. Reddy’s Laboratories, Inc. until after the ’499 and ’458 patents expire.

Count I – Infringement of the ’499 Patent

41. Pozen incorporates by reference and repeats the allegations in paragraphs 1-32, above.

42. Sun's submission of ANDA No. 202-803 to the FDA, including the Paragraph IV Certification to the '499 patent contained therein, constitutes infringement of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

43. Sun's manufacture, use, offer for sale or sale of the Generic Product in the United States, or importation of the Generic Product into the United States, would directly and/or indirectly infringe, either literally or under the doctrine of equivalents, one or more of the claims of the '499 patent.

44. Upon information and belief, Sun was aware of the '499 patent upon submitting ANDA No. 202-803 to the FDA.

45. This case is an exceptional one, and Pozen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II – Infringement of the '458 Patent

46. Pozen incorporates by reference and repeats the allegations in paragraphs 1-37, above.

47. Sun's submission of ANDA No. 202-803 to the FDA, including the Paragraph IV Certification to the '458 patent contained therein, constitutes infringement of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

48. Sun's manufacture, use, offer for sale or sale of the Generic Product in the United States, or importation of the Generic Product into the United States, would directly and/or indirectly infringe, either literally or under the doctrine of equivalents, one or more of the claims of the '458 patent.

49. Upon information and belief, Sun was aware of the '458 patent upon submitting ANDA No. 202-803 to the FDA.

50. This case is an exceptional one, and Pozen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III – Infringement of the '095 Patent

51. Pozen incorporates by reference and repeats the allegations in paragraphs 1-42, above.

52. Sun's submission of ANDA No. 202-803 to the FDA constitutes infringement of the '095 patent under 35 U.S.C. § 271(e)(2)(A).

53. Sun's manufacture, use, offer for sale or sale of the Generic Product in the United States, or importation of the Generic Product into the United States, would directly and/or indirectly infringe, either literally or under the doctrine of equivalents, one or more of the claims of the '095 patent.

54. This case is an exceptional one, and Pozen is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Prayer for Relief

In view of the foregoing, Pozen respectfully requests the following relief:

A. A judgment that Sun's submission of ANDA No. 202-803 constitutes infringement of one or more claims of the '499 patent;

B. A judgment that Sun's submission of ANDA No. 202-803 constitutes infringement of one or more claims of the '458 patent;

C. A judgment that Sun's submission of ANDA No. 202-803 constitutes infringement of one or more claims of the '095 patent;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Sun's ANDA shall not be earlier than the expiration date of the '499 patent, including any extensions thereof;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Sun's ANDA shall not be earlier than the expiration date of the '458 patent, including any extensions thereof;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Sun's ANDA shall not be earlier than the expiration date of the '095 patent, including any extensions thereof;

G. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Sun, its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Sun or any of the foregoing, from the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of the Generic Product;

H. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285.

I. Costs and expenses incurred in pursuing this action; and

J. Any other relief the Court deems just and proper.

Dated: June 18, 2012

Respectfully submitted,

/s/ *Stephen M. Hash*
Stephen M. Hash

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 18th day of June, 2012.

/s/ Stephen M. Hash
Stephen M. Hash